April 19, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers lane
RM 1061
Rockville, MD 20852

Novo Nordisk Pharmaceuticals, Inc.
Suite 200
100 Overlook Center
Princeton, NJ 08540-7810
Tel. 609-987-5800
Fax 609-921-8082

RE: Docket No. 00D-0087

Dear Sir/Madam:

Herein are provided comments on behalf of Novo Nordisk Pharmaceuticals, Inc. on the draft *Guidance for Industry – IND Meetings for Human Drugs and Biologics/ Chemistry, Manufacturing, and Controls Information.*

Lines 46 to 50 (II B Meeting Request)
Section II General Aspects states that "the general aspects of meetings provided in this guidance summarize the information provided in the formal meetings and fast track drug development guidances listed in section I and supplement this information with respect to CMC". Section II B mentions only that "for general information on procedures for written meeting requests, sponsors should refer to the regulations, guidances, and policies and procedures listed in section I". The reference to section I is not found sufficient and having the statement in Section II General Aspects in mind it is proposed to give more detailed information in the Meeting Request section. It is proposed to add, "FDA will honor requests for CMC meetings except in the most unusual circumstances (e.g., submitted information or data are inadequate for meaningful Agency comment). CMC meetings should be scheduled to occur within 60 days of the Agency's receipt of the written request for a meeting. If the sponsor or applicant requests a date for the meeting that is beyond 60 days from the date the Agency receives the request, the meeting should be scheduled to occur no later than 14 days after the date requested" and "The Division Director or delegate in the FDA component who receives a request for a meeting should promptly determine whether to hold the meeting. The review division should respond to the sponsor or applicant within 14 days of receipt of the meeting request. If FDA agrees to the meeting, the written response (i.e., letter or fax) should include the date, time, length, and place of the meeting as well as the expected FDA participants. If a meeting request is denied, the notification to the sponsor or applicant should include a clear explanation of the reason(s) for the denial (e.g., the meeting request was inadequate)." Similar sections are included in the FDA guidance for industry: Formal Meetings with Sponsors and Applicants for PDUFA Products (February 2000). Addition of the proposed sentences will facilitate the reading of the guidance, and the reader will not need to look into several guidances.

Lines 52 to 64 (II C Information Package)

For the same reasons as given above it is proposed to add, "A sponsor or applicant should submit an information package to FDA so that it is received at least 4 weeks prior to the formal meeting. FDA may postpone or cancel a meeting if supporting documentation essential for a productive meeting has not been received by the Agency within the prescribed time frames." Similar sections are included in the FDA guidance for industry: Formal Meetings with Sponsors and Applicants for PDUFA Products (February 2000). Addition of the proposed sentences will facilitate the reading of the guidance.

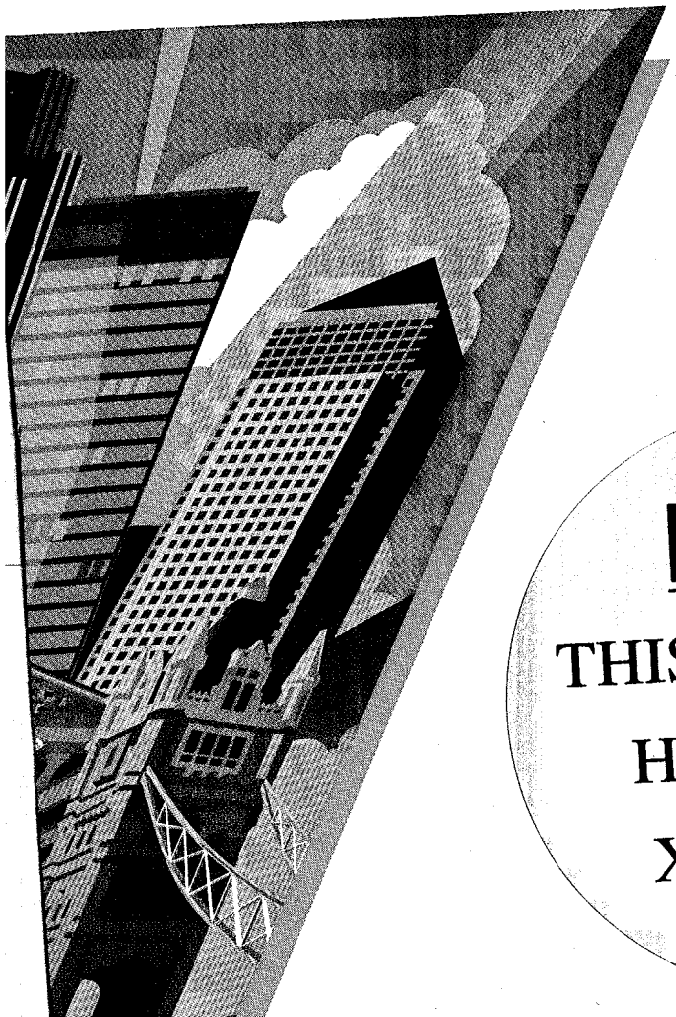
These comments are being submitted in duplicate. If there are any questions please contact Timothy Urschel, Asst. Director Regulatory Affairs, at (609) 987-5940.

Sincerely,
NOVO NORDISK PHARMACEUTICALS, INC.

Barry Reit, Ph.D.
Vice President, Regulatory Affairs

DHL

WORLDWIDE EXPR



FDA

THIS PACKAGE

HAS BEEN

X-RAYED

FR: MAUREEN KELLY
100 OVERLOOK CENTER
SUITE 200
PRINCETON, NJ
08540 UNITED STATES

REF: 000-846016

DATE: 04-19-2000
PH:609 987 5800

TO: FOOD AND DRUG ADMINISTRATION
DOCKETS MANAGEMENT BRANCH
(HFA-305)
5630 FISHERS LANE
RM 1061
ROCKVILLE, MD
20852 UNITED STATES

DESCRIPTION: DOCUMENTS

WEIGHT: 0.20 lbs.

All services are subject to DHL's published service conditions.

U.S. DOMESTIC

DEST:
GAI

Airwaybill: 9397563501
(Non-Negotiable)

9397563501

DHL WORLDWIDE EXPRESS®
333 Twin Dolphin Drive
Redwood City, CA 94065

ORIGIN: TTN
No. of Pcs: 1 OF 1

(EasyShip Unit #3130)

Affix to package.

30

YEARS OF